federal register

TUESDAY, FEBRUARY 13, 1979

PART IV

# ENVIRONMENTAL PROTECTION AGENCY

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# CHLOROBENZILATE

## Notice of Intent to Cancel Registrations and Deny Applications for Registration of Pesticide Products Containing Chlorobenzilate

[6560-01-M]

## ENVIRONMENTAL PROTECTION AGENCY

[FRL 1058-8; OPP-30000/3E]

### CHLOROBENZILATE

**Notice of Intent To Cancel Registrations and Deny Applications for Registration of Pesticide Products Containing Chlorobenzilate Pursuant to Section 6(b)(1) and 3(d) of Federal Insecticide, Fungicide, and Rodenticide Act**

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Cancel Registrations and Deny Applications for Registration of Pesticide Products; Analysis of Comments (Position Document 4) Concerning Chlorobenzilate.

SUMMARY: On May 26, 1976, the Environmental Protection Agency (EPA) published in the FEDERAL REGISTER (41 FR 21517) a notice of rebuttable presumption against registration and continued registration (RPAR) of pesticide products containing chlorobenzilate. Registrants and other interested persons were provided the opportunity to submit data and information to rebut the presumption. After reviewing all available information, the EPA determined that the cancer risk presumption announced in the chlorobenzilate RPAR had not been rebutted, and that the uses of chlorobenzilate posed risks of cancer and adverse testicular effects to certain exposed groups. The Agency also reviewed information relating to the benefits of these uses and, after considering risks in relation to benefits, determined that these risks may be reduced by modifying the terms and conditions of registration for some uses as detailed in this notice and by cancelling or denying applications for other uses. These preliminary decisions were announced in the Notice of Determination Concluding the Chlorobenzilate RPAR, published on July 11, 1978 (Preliminary Notice).

This Notice initiates actions to cancel unconditionally the registrations of the non-citrus uses of chlorobenzilate and to cancel the registrations of the citrus uses of chlorobenzilate unless registrants modify the terms and conditions of registration as required by this Notice. This Notice also notifies applicants for new registrations of non-citrus uses that these applications will be denied, and applicants for new registrations of citrus uses that unless they comply with (correct) conditions as required by this Notice and notify the Agency within 30 days, the Agency will refuse to register new citrus uses of chlorobenzilate.

FOR FURTHER INFORMATION CONTACT:

J. B. Boyd, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs (TS-791), Room 447, East Tower, EPA, 401 M St. SW., Washington, D.C. 20460, 202-755-2972.

SUPPLEMENTARY INFORMATION: Position Document 4 (PD 4), which accompanies this Notice, discusses in detail the comments which were received concerning Position Document 3 (PD 3) and the Preliminary Notice. The SAP and USDA comments are included in their entirety in PD 4 as Appendix A.

### I. INTRODUCTION

On June 30, 1978 (43 FR 29824; July 11, 1978) the Environmental Protection Agency issued a Notice of Determination pursuant to 40 CFR 162.11(a)(5), terminating the Chlorobenzilate RPAR. The Agency determined that the risks of using chlorobenzilate on citrus crops in Florida, Texas, and California, are greater than the social, economic, and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency further determined that these modifications in the terms and conditions of registration accomplish significant risk reductions, and that these risk reductions can be achieved without significant impacts on the benefits of the uses. In addition, the Agency decided to require registrants and applicants for registration for these citrus uses to conduct additional exposure studies in order to permit the Agency to further refine its exposure estimates.

With respect to the non-citrus uses of chlorobenzilate and the use of chlorobenzilate on citrus crops in Arizona, the Agency determined that the risks of chlorobenzilate use outweigh the benefits, and the Agency initiated action to cancel or deny registrations for these uses.

The remainder of this Notice sets forth in detail the Agency's analysis of the comments submitted by the Secretary of Agriculture, the FIFRA Scientific Advisory Panel (SAP), and other interested parties regarding the reasons and factual bases for the regulatory actions announced in the Notice of Determination.

This Notice is organized into four Sections. This introduction is section I. Section II, titled "Legal Background," is a general discussion of the regulatory framework within which these actions are taken. Section III and the accompanying PD 4 set forth the bases for the decisions. Section IV, titled "Procedural Matters," is a brief discussion of the procedures which will be followed in implementing the regulatory actions which the Agency is announcing in this Notice.

### II. LEGAL BACKGROUND

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide perform its intended function without causing "unreasonable adverse effects" on the environment [section 3(c)(5)]. "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" (FIFRA, section 2(bb)). In effect, this standard requires a finding that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with the terms and conditions of registration, or in accordance with commonly recognized practice. The manufacturer's burden of proving that a pesticide satisfies the registration standard continues as long as the registration remains in effect. Under section 6 of FIFRA the Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.[1]

The Agency created the RPAR process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide a structure for gathering and evaluating information about the risks and benefits of these uses. This structure invites public participation at major points in the evaluation process.

The RPAR process is set forth at 40 CFR 162.11. This section provides that

[1] The statutory standard for registration also requires that the pesticide satisfy the labeling requirements of FIFRA. These requirements are set out in the statutory definition of "misbranded" [FIFRA Section 2(q)]. Among other things, this Section provides that a pesticide is misbranded if "the labeling . . . does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any * * * [restrictions] imposed under section 3(d) * * * are adequate to protect health and the environment." The Agency can require changes to the directions for use of a pesticide in most circumstances either by finding that the pesticide is misbranded if the labeling is not changed, or by finding that the pesticide would cause unreasonable adverse effects on the environment, unless labeling changes are made which accomplish risk reductions.

a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to man or the animal or plant of concern with regard to the adverse effect in question.[2] Further, in addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social, and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use.

The regulations require the Agency to conclude an RPAR by issuing a Notice of Determination. In that Notice, the Agency states and explains its position on the question whether the risk presumption has been rebutted. If the Agency determines that the presumption is not rebutted, it then considers information relating to the social, economic, and environmental costs and benefits which registrants and other interested persons submitted to the Agency, and any other benefits information known to the Agency. If the Agency determines that the risks of a pesticide use appear to outweigh its benefits, the RPAR process finally concludes with a Notice of Intent to Cancel or Deny Registration, pursuant to FIFRA section 6(b)(1) or section 3(c)(6).

When the uses of a pesticide appear to pose risks which are greater than benefits, the Agency considers modifications to the terms and conditions of registration which can reduce risks, and the impacts of such modifications in the terms or conditions of registration on the benefits of the use. The risk reduction measures, short of cancellation, which are available to the Agency include requiring changes in the directions for use on the pesticide's labeling, and classifying the pesticide for "restricted use", pursuant to FIFRA, section 3(d).

The statute requires the Agency to submit notices issued pursuant to section 6 to the Secretary of Agriculture for comment and to provide the Secretary of Agriculture with an analysis of the impact of the proposed action on the agricultural economy [section 6(b)]. The Agency is required to submit these documents to the Secretary at least 60 days before making the Notice effective by sending it to registrants or making it public. The Secretary of Agriculture is required to comment in writing within 30 days of receiving the Notice, and the Agency is required to publish the Secretary's comments and the Administrator's response with publication of the Notice. The statute also requires the Administrator to submit Section 6 notices to a Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment, at the same time and under the same procedures as those described for review by the Secretary of Agriculture [FIFRA section 25(d)].

Although not required to do so under the statute, the Agency decided that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decision-making to afford an opportunity to registrants and other interested persons to comment on the bases for the proposed action during the time that the proposed action is under review by the Secretary of Agriculture and the SAP. Accordingly, the Preliminary Notice and PD 3 were made available to registrants and other interested persons at the time the decision documents were transmitted for formal external review (The Preliminary Notice was published in the FEDERAL REGISTER; interested persons were notified that PD 3 was available through publication of a Notice of Availability in the FEDERAL REGISTER and by other means). Registrants and other interested persons were allowed the same period of time to comment, 30 days, that the statute provides for receipt of comments from the Secretary of Agriculture and the SAP. The Agency extended this period to allow time for a public meeting to be held during the comment period; this amounted to a 17-day extension. Moreover, the Agency considered comments received after this date, to the extent it was possible to do so, consistent with orderly decision making.

### III. DETERMINATIONS AND ANNOUNCEMENT OF REGULATORY ACTIONS

As detailed in the Preliminary Notice and PD 3, the Agency considered information on the risks associated with the uses of chlorobenzilate, including information submitted by registrants and other interested persons in rebuttal to the chlorobenzilate RPAR. The Agency also considered information on the social, economic, and environmental benefits of the uses of chlorobenzilate subject to the RPAR, including benefits information submitted by registrants and other interested persons in conjunction with their rebuttal submissions and information submitted by the United States Department of Agriculture. The Agency's assessment of the risks and benefits of the uses of chlorobenzilate subject to this RPAR, its conclusions and determinations on whether any uses of chlorobenzilate pose unreasonable adverse effects on the environment, and its determination on whether modifications in terms or conditions of registration reduce risks sufficiently to eliminate any unreasonable adverse effects, were summarized in the Preliminary Notice and set forth in detail in PD 3. PD 3 was adopted by the Agency as its statement of reasons for the determinations and actions announced in the Preliminary Notice and as its analysis of the impacts of the proposed regulatory actions on the agricultural economy.

This Notice constitutes the Agency's Final Notice of Determination Concluding the Chlorobenzilate RPAR. It reflects modifications in the Agency's initial determinations on the risks, benefits, and unreasonable adverse effects of chlorobenzilate pesticide uses which the Agency has concluded are appropriate, after review of the comments and information received concerning PD 3 and the Preliminary Notice from the Secretary of Agriculture, the SAP, and other sources. This Notice also reflects the modifications in the regulatory actions announced in the Preliminary Notice which the Agency has concluded are appropriate, in light of the comments and other information received on PD 3 and the Preliminary Notice from all sources. PD 4, which accompanies this Notice, discusses in detail the information that was received,[3] and the Agency's

[2] 40 CFR 162.11(a)(4) provides that registrants and applicants may rebut a presumption against registration by sustaining the burden of proving: "(1) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3)(i) or (iii) that when considered with the formulation, packaging, method of use, and proposed restrictions and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or (ii) in the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist, or accrue to levels in man or the environment likely to result in any significant chronic adverse effects; or (iii) that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error. A primary purpose of the RPAR process is to screen for appropriate action those pesticide uses which pose risks which are of sufficient concern to require the Agency to consider whether offsetting benefits justify the risks. Accordingly, the Agency's approach to rebuttal determinations concentrates on whether the risk concerns which are central to each RPAR proceeding have in fact been answered.

[3] The comments received from the SAP and the Secretary of Agriculture are attached as Appendix A to PD 4. All other

Footnotes continued on next page

reasons for changing or not changing its initial determinations and the regulatory actions announced in the Preliminary Notice. Finally, this Notice announces the regulatory actions which the Agency is implementing concerning chlorobenzilate. The Agency hereby incorporates PD 3 and PD 4 as its statement of reasons for these actions.

### A. DETERMINATIONS ON RISKS

The chlorobenzilate RPAR was based on laboratory studies showing that chlorobenzilate induced oncogenic effects in experimental mammalian species. The Agency has determined that the presumption that chlorobenzilate poses an oncogenic risk was not rebutted. The Agency has determined that two of the studies which formed the basis for the Chlorobenzilate RPAR were insufficiently reliable to assess the oncogenicity of chlorobenzilate. However, the Agency has further determined that several other studies provide a reliable basis for concluding that chlorobenzilate induces oncogenic effects in experimental mammalian species, and that under the Agency's Interim Cancer Assessment Guidelines, these laboratory studies provided substantial evidence that chlorobenzilate poses a cancer risk to humans. The Agency has further determined that human exposure may result form the uses of chlorobenzilate, and that chlorobenzilate use therefore poses a cancer risk to man of sufficient magnitude to require the Agency to determine whether the uses of chlorobenzilate offer offsetting social, economic, or environmental benefits. The Agency identified the key populations at risk with respect to chlorobenzilate use: the U.S. populations at large, Florida residents, pesticide applicators, and citrus pickers.

The Agency has further determined that exposure levels to male pesticide applicators are high enough, in comparison to the "no observable effect" levels for adverse testicular effects in rats, to warrant a conclusion that chlorobenzilate may pose a risk of adverse effects to the testes of applicators of sufficient magnitude to require the Agency to determine whether offsetting social, environmental, or economic benefits result from the uses of the pesticide.

### B. DETERMINATIONS ON BENEFITS

The uses of chlorobenzilate which are subject to this notie are grouped into two categories: Citrus uses, and other uses.[4]

1. *Citrus uses.* Chlorobenzilate is used on citrus crops in Florida, Texas, California, and Arizona to control mites. Most of this use (72%) occurs in Florida. Significant adverse economic and environmental impacts would occur if mite pests were controlled by alternative miticides. Chlorobenzilate is used in citrus integrated pest management ("IPM") because it is selective to mites and does not kill predators and parasites of citrus scale pests. Such integrated pest management approaches are used extensively in Florida, to a lesser extent in most other citrus growing regions, and IPM programs are planned in Arizona. These are several other selective miticides registered for use on citrus crops, and a number of nonselective miticides are registered for use on citrus crops.

With respect to Florida, the Agency has determined that chlorobenzilate cancellation would cause significant increases in pest control costs. Nonselective miticides would be the predominant replacements for chlorobenzilate, for economic and other reasons developed in detail in PD 3. This would necessitate abandonment of IPM control of scale insects because of reduction in populations of beneficial insects (i.e., scale parasites), and the subsequent use of large volumes of chemical pesticides to control scale insects.

In Texas, pest control costs would also increase if chlorobenzilate were cancelled. Economic and other factors favor adoption of selective alternatives to a greater extent in Texas than in Florida. However, the selective alternatives appear to pose risk problems which warrant caution in encouraging their increased use.

Relatively small amounts of chlorobenzilate are used in California on a few citrus corps in one area. However, its use is almost entirely in connection with integrated pest control. Cancellation of chlorobenzilate for this use would have a significant economic impact, because there are no registered alternatives that the Agency believes are suitable chlorobenzilate replacements.

Although the loss of chlorobenzilate and the adoption of alternative miticides is projected to have no net economic impact to Arizona citrus growers, the use fo alternatives could disrupt projected IPM strategies in Arizona and lead to more environmentally adverse pest management practices.

2. *Other uses.* With respect to the other uses of chlorobenzilate, the Agency has determined that registered alternatives are available for each use; in some cases the alternatives are less expensive than chlorobenzilate, and achieve comparable levels of control.

### C. DETERMINATIONS ON UNREASONABLE ADVERSE EFFECTS

The Agency has made the following unreasonable adverse effect determinations with respect to the uses of chlorobenzilate subject to this RPAR:

1. *Determinations on citrus uses.* The Agency has determined that the risks of the citrus uses of chlorobenzilate in Florida, Texas, California, and Arizona are greater than the social, economic, and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has further determined that these modifications in the terms and conditions of registration accomplish significant risk reductions, and that these risk reductions can be achieved without significant impacts on the benefits of the uses. Accordingly, the Agency has determined that unless these changes in the terms and conditions of registration are accomplished, the citrus uses of chlorobenzilate in Florida, Texas, California and Arizona will generally cause unreasonable adverse effects on the environment, when used in accordance with widespread and commonly recognized practice, and that the labeling of chlorobenzilate pesticide products for citrus uses will not comply with the provisions of FIFRA.

2. *Determinations on uses other than the citrus use.* The Agency has determined that the uses of chlorobenzilate other than the citrus use which are subject to this notice pose risks which are greater than the social, economic, and environmental benefits of the use. Accordingly, the Agency has determined that these uses of chlorobenzilate will generally cause unreasonable adverse effects on the environment when used in accordance with commonly recognized practice; the notice of intent to cancel these uses is hereby announced.

### D. OTHER DETERMINATIONS

The Agency has determined that registrants and applicants for registration of chlorobenzilate products for citrus uses must develop and submit to the Agency within 1 and ½ years the additional exposure studies described in Section IV of PD 3. The Agency will use the exposure data for the purpose of refining its exposure estimates with

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comments are available for public inspection in the chlorobenzilate public file, except for limited portions of some comments which are protected from public disclosure by FIFRA, section 10.

[4] The category of "other" uses consists of these agricultural crops: cotton; fruits, and nuts (apples, pears, cherries, almonds, and walnuts); melons (casaba, cantaloupes, crenshaw, honeydew, Persian); ornamentals (lawns and turf), grass (herbaceous plants and bulbs) aster, carnations, chrysanthemums, gladioli, iris, marigold, phlox, snapdragon, zinnia; (woody shrubs, trees and vines) arbovitae, azaleas, birch, boxwood, camellia, Douglas fir, elm, hawthorn, hemlock, holly, juniper, lilac, locust, maple, oak, ornamental shrubs, ornamental trees, pine, poplar, rhododendron, roses, spruce, willow yew; domestic dwellings, medical facitities and schools, commercial establishments (areas other than edible product areas) outdoor areas, boats, and docks.

respect to the citrus uses of chlorobenzilate, and re-assessing its conclusions that use of chlorobenzilate on citrus crops in Florida, Texas, California, and Arizona, in accordance with the modifications to the terms or conditions of registration determined herein to be necessary, does not cause unreasonable adverse effects on the environment.

The rat reproductive study described in PD4 will be used by the Agency to further evaluate the safety of these uses.[5]

### E. ANNOUNCEMENT OF REGULATORY ACTIONS

Based upon these determinations, the Agency is initiating the following regulatory actions, and this document shall constitute its notice of intent regarding these actions:

1. Cancellation and denial of registrations of chlorobenzilate products for uses other than citrus uses in Florida, Texas, California, and Arizona.

2. Cancellation and denial of registrations of chlorobenzilate products registered for use on citrus crops in Florida, Texas, California, and Arizona, unless registrants or applicants for registration modify the terms or conditions of registration as follows: [6]

a. Classification of chlorobenzilate products for these citrus uses for restricted use, for use only by or under the direct supervision of certified applicators.

b. Modification of the labeling of chlorobenzilate products for these citrus uses to include the following:

(1) *Restricted Use Pesticide*

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

(2) *General Precautions*

a. Take special care to avoid getting chlorobenzilate in eyes, on skin, or on clothing.

b. Avoid breathing vapors or spray mist.

c. In case of contact with skin, wash as soon as possible with soap and plenty of water.

d. If chlorobenzilate gets on clothing, remove contaminated clothing and wash affected parts of body with soap and water. If the extent of contamination is unknown, bathe entire body thoroughly. Change to clean clothing.

e. Wash hands with soap and water each time before eating, drinking, or smoking.

f. At the end of the work day, bathe entire body with soap and plenty of water.

g. Wear clean clothes each day and launder before reusing.

(3) *Required Clothing and Equipment for Application*

a. One-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the *USDA/EPA Guide for Commercial Applicators.*

b. Wide-brimmed hat.

c. Heavy-duty fabric work gloves.

d. Any article which has been worn while applying chlorobenzilate must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be buried or burned.

e. Facepiece respirator of the type approved for pesticide spray applications by the National Institute for Occupational Safety and Health.

f. Instead of the clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply. Aerial application may be conducted without the specified clothing and equipment.

(4) *Handling Precautions*

Heavy duty rubber or neoprene gloves and apron must be worn during loading, unloading, and equipment clean-up.

In addition to these actions, the Agency will soon be initiating action to require the additional exposure studies referred to earlier to be accomplished and submitted to the Agency. This action is required by this notice, but will be implemented by subsequent correspondence from the Registration Division, Office of Pesticide Programs, to registrants and applicants for registration of chlorobenzilate products for citrus uses.

### IV. PROCEDURAL MATTERS

This Notice initiates actions to cancel unconditionally the registrations of the non-citrus uses of chlorobenzilate and to cancel the registration of the citrus uses of chlorobenzilate unless registrants modify the terms and conditions of registration as required by this Notice. This Notice also notifies applicants for new registrations of non-citrus uses that these applications will be denied, and applicants for new registrations of citrus uses that unless they comply with (correct) conditions as required by this Notice and notify the Agency on or before March 15, 1979, the Agency will refuse to register new citrus uses of chlorobenzilate.

Under Sections 6(b) and 3(d) of FIFRA, applicants, registrants, and other interested or affected parties may request a hearing on the cancellation and denial actions that this Notice initiates. This Section of the Notice explains how affected persons may request a hearing, and the consequences of requesting or failing to request a hearing in accordance with the procedures specified in this Notice.

### A. PROCEDURE FOR REQUESTING A HEARING

1. *When a hearing must be requested for cancellation actions.* Registrants affected by the actions initiating cancellation of the registered uses of chlorobenzilate may request a hearing on specific registered uses within 30 days of receipt of this notice, or on or before March 15, 1979, whichever occurs later. Any person adversely affected by the cancellation actions initiated by this notice may request a hearing on specific registered uses affected by this notice on or before March 15, 1979.

2. *When a hearing must be requested for actions to deny applications.* Applicants for new registration of the uses affected by this notice may request a hearing on specific uses within 30 days of receipt of this notice or on or before March 15, 1979, whichever occurs later. Other interested persons may request a hearing with the concurrence of the applicant during the time period available to the applicant.

3. *How to request a hearing.* All registrants, applicants, and other interested or affected parties who request a hearing must file the request in accordance with the Agency's Rules of Practice Governing Hearings (40 CFR, Part 164). These procedures specify among other things, that: 1) all requests for a hearing must be accompanied by objections that are specific for each use for which a hearing is requested [40 CFR 164.20(b)], and 2) that all requests must be received by

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[5] For the Agency's authority to require registrants to conduct studies relevant to assessing the risks and benefits of a pesticide, and to report the results thereof to the Agency, see FIFRA section 3(c)(2)(B).

[6] FIFRA section 6(b)(1) provides that the Administrator may initiate proceedings to cancel a registration or change its use classification, where the Administrator finds that the pesticide does not satisfy the statutory standard for registration. However, the registered chlorobenzilate products subject to this action have not yet been initially classified. Accordingly, any classification action with respect to these products is an initial classification, and not a change in classification. Initial classification generally does not give rise to a right to review the classification decision in an adjudicatory hearing. [See Preamble to *Optional Procedures for Classification of Pesticide Uses by Regulation*, 43 FR 5782, 5784 (Feb. 9, 1978)]. However, in view of the fact that the Agency is proposing other changes to the terms or conditions of the registration (e.g. labeling changes) for registered chlorobenzilate products, which are reviewable in adjudicatory hearings, the Agency has determined that it is appropriate to exercise its discretion to fashion procedures in excess of minimum statutory requirements, and to permit the question of whether chlorobenzilate products for citrus uses should be initially classified for restricted use and its use limited to certified applicators to be reviewed in any such adjudicatory hearing as well.

the Hearing Clerk within the applicable thirty (30) day time period [40 CFR 164.5(a)]. Failure to comply with these requirements will automatically result in denial of the request for a hearing.

Requests for hearings must be submitted to:

Hearing Clerk (A-110), U.S. Environmental Protection Agency, 401 M St. S.W., Washington, D.C. 2060.

B. CONSEQUENCES OF FILING OR FAILING TO FILE A HEARING REQUEST

1. *Consequences of filing a timely and effective hearing request.* If a hearing on the Administrator's intent to cancel the citrus and/or non-citrus uses of chlorobenzilate is requested in a timely and effective manner before the end of the 30-day notice period, the hearing will be governed by the Agency's rules of practice for hearings under FIFRA Section 6 (40 CFR, Part 164). In the event of a hearing, the cancellation and denial actions subject to the hearing will not become effective except pursuant to orders of the Administrator at the conclusion of the hearings.

2. *Consequences of failure to file in a timely and effective manner.* If a hearing on the Administrator's intent to cancel the non-citrus uses of chlorobenzilate is not requested in accordance with the procedures specified above within the 30-day notice period, cancellation of the non-citrus uses of chlorobenzilate becomes final and effective at the end of the 30-day notice period.

If a hearing on the Administrator's intent to cancel conditionally the citrus uses of chlorobenzilate is not requested in accordance with the procedures specified above within the 30-day notice period, immediately after this 30-day notice period, the Agency will notify registrants and applicants of the procedures for amendment of their registrations and applications in accordance with the determinations specified in this notice. This notification will establish the date(s) on which the cancellations will become effective if registrants do not apply to amend their registrations as required by this notice, and will provide other necessary instructions and information.

Dated: February 5, 1979.

STEVEN D. JELLINEK,
*Assistant Administrator for Toxic Substances.*

CHLOROBENZILATE POSITION DOCUMENT 4

SPECIAL PESTICIDE REVIEW DIVISION, OFFICE OF PESTICIDE PROGRAMS, OFFICE OF TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

CHLOROBENZILATE

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## I. INTRODUCTION

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. Section 136 *et seq.*), the Environmental Protection Agency (EPA or the Agency) regulates all pesticide products. Section 6(b) of FIFRA authorizes the Administrator of the EPA to issue a notice of intent to cancel the registration of a pesticide or to change its classification if it appears to him that the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with wide-spread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." Section 3(c)(6) authorizes the Administrator to deny applications for pesticide registration if the statutory standards for registration are not met.

The Agency designed the Rebuttable Presumption Against Registration (RPAR) process to gather risk and benefit information about problem pesticides and to make balanced decisions concerning them in a manner which allows all interested groups to participate. This process is set forth in 40 CFR 162.11.

On May 26, 1976, the Agency issued an RPAR notice for pesticide products containing chlorobenzilate (41 FR 21517, May 26, 1976). The chlorobenzilate RPAR was one of the first issued by the Agency. At the time it was issued, Agency RPAR procedures were still in a formative stage, and a detailed Position Document 1 did not accompany the chlorobenzilate RPAR notice.

On June 30, 1978, the Agency issued Position Document 3 for chlorobenzilate, and published a notice of determination and availability of the position document in the FEDERAL REGISTER on July, 11, 1978 (43 FR 29824-29828). In Position Document 3 the Agency analyzed the rebuttals it received in response to the original RPAR notice, presented its analysis of both the risks and benefits associated with the uses of chlorobenzilate, and proposed a decision to conclude the RPAR process.

40 CFR 162.11 requires the Agency to submit notices issued pursuant to Section 6 to the Secretary of Agriculture for comment on the impact of the proposed action on the agricultural economy [Section 6(b)] and to a Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment [Section 25(d)]. The Agency is required to submit these documents to the Secretary and the SAP at least 60 days before making the notice effective by sending it to registrants or making it public. The Secretary of Agriculture and SAP are invited to comment in writing within 30 days of receiving the notice, and the Agency is required to publish their comments and the Administrator's response with publication of the notice.

Although not required to do so under the statute, the Agency has decided that it is consistent with the purposes of the RPAR process and the Agency's overall policy of open decision-making to afford registrants and other interested persons an opportunity to comment on the bases for the proposed action while it is under review by the Secretary of Agriculture and the SAP.

The Agency has received a number of comments in response to the June 30, 1978 Notice of Determination and the Chlorobenzilate Position Document 3. The Agency also considered comments which were received after the mandatory 30-day period allowed by law. All comments received either during or after the 30-day period were made available in the public file for review and evaluation by the public. Responses from the SAP, the U.S. Department of Agriculture, and other interested parties have been analyzed and are addressed in Section II of this document. Section III summarizes the Agency's decision concerning pesticide products containing chlorobenzilate. The responses from the SAP and the USDA are contained in Appendix A in their entirety.

## II. ANALYSIS OF COMMENTS

The Agency received comments from the Secretary of Agriculture, the Scientific Advisory Panel (SAP), and 15 other concerned individuals and organizations. These comments are organized by topic and discussed below. As indicated in the following discus-

sion, the Agency has revised some aspects of its assessment of risks, benefits, and regulatory requirements in accordance with USDA, SAP, and other recommendations. Except as discussed below, other aspects of the analyses presented in Position Document 3 are unchanged.

A. COMMENTS RELATING TO RISK

1. *EPA Risk Assessment.* The chlorobenzilate risk assessment was based in part on data from studies by Innes and the National Cancer Institute (NCI) which showed that chlorobenzilate produced statistically significant increases in the incidence of tumors in male mice ingesting the pesticide.

a. *Problems in Extrapolating Risk to Actual Human Populations.* One commenter [42 (30000/3D)] stated that, "EPA's (cancer) risk assessment does not account for the heterogeneity of the human population and subpopulations of more susceptible individuals compared to the homogeneity of animal populations in test situations. It also does not account for the fact that human populations exposed to chlorobenzilate, as opposed to test animal populations, are composed of sick and poorly nourished individuals as well as healthy people. Further, the EPA assessment does not account for possible greater sensitivity of the human population than even the most sensitive rodent species tested. Finally, CAG's assessment does not account for synergistic effects from exposure to other toxic chemicals in the human environment to which humans are exposed."

First, the Agency notes that the risk assessment, like many other aspects of the Agency's risk/benefit analysis, is based on various relevant factors, data, and considerations. However, not all such factors are known to the Agency or usable in the risk/benefit analysis. In many cases the nature of and limits on the Agency's estimates for chlorobenzilate are detailed and explained in Position Document 3. Because uncertainties such as synergism and heterogeneity exist, the Agency used the most conservative model and test results from the most sensitive group of test animals to extrapolate to humans the cancer risk associated with chlorobenzilate.

More specifically, with respect to heterogeneity, the straight-forward simplified model of population effects used by the Carcinogen Assessment Group (CAG) is a probabilistic model which only attempts to estimate the overall impact of the use of the compound. The Agency recognizes that some people will be more sensitive than the average and others will be less sensitive, but no detailed information about the distribution of sensitivities is available. It is, therefore, impossible to factor this kind of information into a risk estimate.

With respect to synergism, one of the many uncertainties in estimating the risk to humans is the concomitant exposure to other chemicals along with chlorobenzilate. Some of these chemicals could have additive effects, whereas others could potentiate or counteract the effects of chlorobenzilate. As with heterogeneity, the Agency cannot factor this kind of information into a risk estimate because no realistic model of the nature and amounts of the background exposure to other chemicals is available.

b. *Innes Study Deficiencies.* One commenter [40 (30000/3D)] outlined what he believed to be significant deficiencies in the Innes study. Specifically, this commenter argued that the physical location of the animals which were fed chlorobenzilate in relation to the positive control groups may have resulted in contamination of the treated animals by other chemicals which could have caused the tumors and, therefore, invalidated the study.

The Agency found that in the Innes study many groups of animals were kept in the same room; this included 27 groups of animals on which various pesticides were being tested, including the animals which were being fed chlorobenzilate and the positive and negative controls. While the current practice is to avoid co-housing of this type, the possibility that contamination affected the outcome of the study is low since the untreated controls did not develop tumors, and only 3 of the 27 other groups of animals being tested showed an increase in tumor incidence.

This commenter also contended that the Agency's risk estimate should have been based on the tumor incidence among female mice of the NCI study using a time-to-tumor model.

The Agency generally uses the more conservative linear model and the most sensitive group of test animals (in the case of chlorobenzilate, male mice from the NCI study as well as the male mice from the Innes study) in developing its risk estimates. This is based on the fact, as discussed above, that there are many uncertainties which the Agency cannot factor into a risk estimate, such as species difference, susceptible subgroups of the human population, lack of adequate data about human exposure, and the synergistic effect of chemicals, which make a more conservative approach to assessing cancer risk to humans preferable to a liberal one.

Another commenter [42 (30000/3D)] submitted a published pathological review (Reuber, M.D., *Digestion* 16: 308, 1977) of the Innes study in support of its validity in indicating oncogenic risk. The CAG recognized and cited this paper in their final assessment of chlorobenzilate.

2. *Dietary Risks.* The general population of the United States was identified in Position Document 3 as being potentially at risk from exposure to chlorobenzilate in the diet. Florida residents may ingest additional amounts of chlorobenzilate because pulp from chlorobenzilate-treated citrus fruit is fed to dairy cattle and beef cattle which are raised and marketed in Florida. Thus, residents of Florida may be indirectly exposed to chlorobenzilate in milk and meat as well as directly exposed to chlorobenzilate from treated citrus fruit, while the general population in the rest of the United States is potentially exposed to chlorobenzilate residues only from treated citrus fruit and citrus fruit byproducts (Position Document 3, pp. 25-27).

a. *Risk to General Population.* The Secretary of Agriculture [36 (30000/3)] recommended that the Agency recalculate the dietary exposure estimates "based on obtainable analytical sensitivity. In addition, these theoretical calculations should be replaced with actual exposure data as it becomes available. The frequency of positive chlorobenzilate residue traces should also be taken into account in calculating theoretical exposure levels."

To recalculate dietary exposure estimates based on the most sensitive analytical methods which are currently available might lead the Agency to underestimate the actual exposure, since most of the monitoring data were obtained with less sensitive methods. Therefore, this suggestion is not acceptable.

By the same reasoning, the suggestion to take into account the frequency of positive samples in the monitoring data was also rejected, since the Agency cannot be sure that samples which appeared to be negative did not actually have chlorobenzilate residues which could have been detected if more sensitive analytical methods had been used. The Agency will, however, revise its estimate of dietary exposure if the required monitoring data indicate that a revision is necessary.

b. *Risk to Infants in Florida.* One commenter [42 (30000/3D)] asserted that the "risk to infants was not factored into CAG's risk assessments," although the CAG forsaw a "risk to infants who could get chlorobenzilate residues from cow's milk via pulp feed as well as through orange juice (Position Document 3, p. 33)." This commenter claimed that according to his calculations, "the dose to child/kg body weight may be greater than 70 times that of an adult."

The Agency recognizes that since milk makes up a large portion of an infant's diet, infants in Florida could be exposed to relatively more chlorobenzilate than adults in Florida, but to the Agency's knowledge, no actual residues of chlorobenzilate have been detected in milk or orange juice intended for human consumption. However, in an attempt to deal with the general possibility of low-level residues, in Position Document 3 Agency scientists projected residues to occur in milk at levels just below the current level of detection.

c. *Revisions in Exposure Analysis.* In order to take account of the higher percentage of milk in an infant's diet, the Agency has recalculated the percentage increase in life-time exposure to chlorobenzilate for infants in Florida. The Agency found that this factor would increase its previous cancer risk estimate by 4% to 14% for infants in Florida (Anderson, 1978b). As indicated by the requirement to develop data on milk and pulp residues (described in pages 85-86 of Position Document 3), this issue is of concern to the Agency. However, the results of the cattle feeding study and milk monitoring data are needed in order to more accurately estimate the additional risk to infants.

Also, the risk associated with milk applies only to the State of Florida, not the entire population of the United States, as the commenter assumed. The additional exposure associated with beef and milk in Table 3 of Position Document 3 refers only to Florida, and has been corrected to indicate this. The revised table appears on page 11.

Although no comments were received on the potential dietary exposure through residues of chlorobenzilate in citrus oil, the Agency is also concerned about this issue. Analyses by EPA laboratories found chlorobenzilate residues of 36 to 53 ppm in orange oil, and 86 and 91 ppm in grapefruit oil, using samples representing "cold-pressed

oil" from eight samples of oranges and two of grapefruit (Kutz, 1978).

The oil content of citrus juices is limited by USDA grading standards to levels varying between 0.015 and 0.03%. For grapefruit juice, the oil content is limited to 0.02%. Thus, the residues which the oil contributes to citrus juices are calculated to be in the range of 0.92 ppm, i.e., 0.02% x 100 ppm in oil.

The only foods where some additional exposure from the use of citrus oil as a flavoring agent can be calculated are fruit-flavored drinks (ready-to-drink, concentrated, and powdered forms). The USDA Household Food Consumption Survey indicates consumption of 19.2 grams/person/day for carbonated fruit-flavored soft drinks and 18.8 grams/person/day for non-carbonated fruit drinks, concentrates, and mixes. Assuming that citrus oil flavorings contribute similar levels of residues to all fruit-flavored soft drinks, concentrates, and powders, as was calculated above for fruit juices, 0.02 ppm x (19.2+18.8 grams)=0.76 μg chlorobenzilate ingested/day. This calculation makes no adjustment for the fact that not all fruit drinks are citrus-flavored (since the Agency has no consumption breakdown), but, on the other hand, does not include the use of citrus oil to flavor foods such as candy, baked goods, and liqueurs.

The additional 0.76 μg/day is roughly 20% of the total dietary chlorobenzilate exposure from fruit (3.8 μg/day) calculated by the EPA in Position Document 3. The Agency has revised its dietary exposure calculations to reflect this additional exposure. This is reflected in Tables 3, 7, and 8 from Position Document 3; these revised tables are included on pages 11, 12, and 13.

[6560-01-C]

TABLE 3

REASONABLE UPPER LIMIT OF DIETARY EXPOSURE TO CHLOROBENZILATE

U.S. Population Exposure

| Commodity | Consumption[a] (g/day) | Extent[b] of Use by Crop (%) | Assumed[c] Maximum Residue (ppm) | Maximum Ingestion (ug/day) |
|---|---|---|---|---|
| Citrus: | | | | |
| Oranges (Inc.juice) | 42.00 | 47.80 | 0.1 | < 2.01 |
| Grapefruit | 19.30 | 60.90 | 0.1 | < 1.18 |
| Other Citrus g/ | 12.70 | 31.00 | 0.1 | < 0.40 |
| Flavored Drinks | 38.00 | - | 0.02 | < 0.76 |
| Other Fruit: | 55.20 | 0.08 | 5.0[d] | < 0.21 |
| Nuts: | 1.18 | 3.60 | 0.1 | < 0.0043 |
| Total U.S. | | | | < 4.56 (0.0024 ppm) |

Florida Population's Additional Exposure[e]

(Percent with Potential Occurrence)[f]

| | | | | |
|---|---|---|---|---|
| Beef and Lamb | 143.2 | 10 | 0.04 | < 0.57 |
| Milk | 184.7 | 100 | 0.0024 - 0.04 | < 0.44 - < 7.39 |
| Total Florida Additional | | | | < 1.01 - < 7.96 |
| Grand Total Florida | | | | < 5.57 - < 12.52 (< 0.0029 - < 0.0065 ppm) |

a/ Severn, 1978
b/ Doane, 1976
c/ Detection level in the most representative sampling
d/ Tolerance level
e/ Feeding by-products of citrus processing (pulp and molasses) to cattle in Florida is viewed as an indirect dietary souce of chlorobenzilate. It results in additional dietary exposure for the Florida population.
f/ Based on limited EPA survey (Luttner and McWhorter, 1978).
g/ Added to account for possible additional residues in citrus oil (Reed, 1978).

TABLE 7

CHLOROBENZILATE

POTENTIAL CANCER RISK THROUGH DIETARY EXPOSURE

FLORIDA POPULATION (8,000,000)

| | Maximum[a/] Lifetime Probability of Tumor Formation (Less Than) | Maximum[b/] Mathematical Expectation of Numbers of Tumors During a Lifetime (Less Than) |
|---|---|---|
| One-hit Model (NCI Data)[c/] | | |
| Observed | 0.6 to 1.3 in 1 million | 5 to 10 |
| One-hit Model (Innes Data)[d/] | | |
| Observed[e/] | 3.1 to 7.0 in 1 million | 25 to 56 |

a/ Assumes that dietary exposure occurs at the level of exposure expressed as reasonable upper limit (0.0025 to 0.0061 ppm daily throughout lifetime), and model projects conservative expression of risk.

b/ Since the animal study was conducted throughout lifetime exposure, the chance of cancer occurrence is extrapolated as the potential of a cancer event during a lifetime, and should, therefore, be interpreted as an index or "mathematical" expectation rather than a "clinical" expectation.

c/ In addition to normal spontaneous rate; estimate based on NCI study male mice with hepatocellular carcinomas [32 out of 48 (treated); 4 out of 19 (controls)] (Albert, 1978b).

d/ In addition to normal spontaneous rate; estimate based on Innes study "Strain X" male mice with hepatomas [9 out of 17 (treated); 8 out of 79 (controls)] (Albert, 1978).

e/ Estimate used.

TABLE 8

CHLOROBENZILATE

POTENTIAL CANCER RISK THROUGH DIETARY EXPOSURE

U.S. POPULATION (EXCEPT FLORIDA) (212,000,000)

| | Maximum[a/] Lifetime Probability of Tumor Formation (Less Than) | Maximum[b/] Mathematical Expectation of Numbers of Tumors During a Lifetime (Less Than) |
|---|---|---|
| One-hit Model (NCI Data)[c/] | | |
| Observed | 0.5 in 1 million | 106 |
| One-hit Model (Innes Data)[d/] | | |
| Observed[e/] | 2.6 in 1 million | 551 |

a/ Assumes that dietary exposure occurs at the level of exposure expressed as reasonable upper limit (0.0025 to 0.0061 ppm daily throughout lifetime), and model projects conservative expression of risk.

b/ Since the animal study was conducted throughout lifetime exposure, the chance of cancer occurrence is extrapolated as the potential of a cancer event during a lifetime, and should, therefore, be interpreted as an index or "mathematical" expectation rather than a "clinical" expectation.

c/ In addition to normal spontaneous rate; estimate based on NCI study male mice with hepatocellular carcinomas [32 out of 48 (treated); 4 out of 19 (controls)] (Albert, 1978b).

d/ In addition to normal spontaneous rate; estimate based on Innes study "Strain X" male mice with hepatomas [9 out of 17 (treated); 8 out of 79 (controls)] (Albert, 1978).

e/ Estimate used.

[6560-01-M]

3. *Testicular Effects.* The presumption against chlorobenzilate was based on the risk of oncogenic effects. However, in re-evaluating long-term chlorobenzilate feeding studies in connection with the RPAR review, the Agency concluded that the data on testicular effects also required consideration. Upon re-examination, the Agency found that testicular toxicity in rats had been reported in five studies. In Position Document 3 [Section II(A)(3)], the Agency analyzed the risk of testicular effects associated with chlorobenzilate.

The Agency received a letter from a registrant on June 22, 1978, which contained raw data and an additional statistical analysis which he claimed proved that the reproductive performance of the rats in the Woodard (1965) three-generation reproduction study was not impaired. The Agency issued Position Document 3 on June 30, 1978, and this information was too late to be considered in that document. During the comment period after Position Document 3 was issued, the registrant [40 (30000/3D)] re-stated his statements of June 22nd, and the Agency has now analyzed this information.

In this study, Woodard fed rats 50 ppm chlorobenzilate and subsequent generations 25 or 50 ppm chlorobenzilate. Initially, significantly-reduced mean testicular weights were reported using the Rank Sum Test of Wilcoxon. In 1966, an FDA reviewer [1] said that the reproductive performance of test and control rats was essentially the same. She observed, however, that there could be a difference in the two groups, because of possible diminished testes weights in the first generation of treated males. The reviewer recommended that the question of whether or not the decrease in testicular weights was significant could be resolved by further statistical analysis. In the letter of June 22nd, the registrant noted that the testicular weights of one animal in the group given 50 ppm chlorobenzilate was more than five standard deviations from the group mean. The registrant therefore eliminated the testicular weights of that animal from subsequent analysis. The decrease in testicular weights was then found to be insignificant by one-way analysis of variance and Fischer's Least Squares Difference tests.

Although the registrant's statistical approach changes the analysis for this study, it does not alter the fact that adverse testicular effects have been regularly observed in animals which received chlorobenzilate at high doses in four other studies discussed in Position Document 3. For this reason, the Agency continues to be concerned about the reproductive effects of chlorobenzilate. Accordingly, the Agency will require the registrants to perform a three-generation reproduction study with appropriate protocol as discussed under Section C(4) of this document.

B. COMMENTS RELATING TO BENEFITS

The Agency's analysis of the benefits associated with chlorobenzilate was presented in Position Document 3 (pp. 39-67). The Agency invited information on the economic, social, and environmental benefits of the pesticide during the rebuttal period, and this information was included in the Chlorobenzilate Benefit Analysis in Position Document 3. The USDA also aided the Agency in a joint effort to develop information on the benefits of the ongoing uses of chlorobenzilate. Several commenters raised questions on the benefits information. This Section also contains new information that has become available since the publication of Position Document 3.

1. *General.* One commenter [50 (30000/3)] wrote, "Concerning chlorobenzilate, there were two major problems with the benefit data. First, it was incomplete * * *."

The chlorobenzilate benefits assessment team (BAT) [2] used only the most current and relevant data which was available to them when they prepared their 1977 report. The BAT was aware of the references cited by this commenter, even though not all of these references were discussed or referenced specifically in the BAT report. The information presented by the commenter either supports the Agency's position or is not the most relevant, current, or accurate data available on the subject (Knapp, 1978a).

This commenter [50 (30000/3)] continued: The second deficiency of the chlorobenzilate benefit data was the use of the Allen paper itself. * * * Incidentally, grapefruit were not mentioned in the Allen paper, but a 17% yield loss of grapefruit was attributed to the Allen paper. Where did the number come from?

The actual objection to Allen's paper is not clear. Jon Allen is a leading expert doing research on how mites damage citrus fruit, foliage, trees, and groves. His results are the most precise and timely available, and his work includes both oranges and grapefruit. Additional data regarding yield are discussed in Section II (4)(a) of this document.

2. *Alternatives.*—a. *Dicofol.* One commenter [39 (30000/3D)] disagreed with the Agency's conclusion that dicofol was not a satisfactory alternative to chlorobenzilate. He first questioned the Agency's representation of the problem of controlling snow scale when dicofol is used as a miticide. Specifically, Position Document 3 stated that, "If dicofol is used in groves infested with snow scale (approximately 75% of Florida groves) the snow scale populations increase, causing serious infestation and necessitating the use of scalicides (Florida Cooperative Extensive Service, 1977)," and "Growers using dicofol in place of chlorobenzilate in groves infested with snow scale would need to supplement dicofol applications with scalicide applications."

The phenomenon of dicofol's effect upon snow scale populations (rapid increases after application in groves where this pest is present) is well documented in the literature (Brooks and Whitney, 1976). Application of dicofol for mite control when snow scale are also present in the grove necessitates the concurrent use of a scalicide, many of which have a negative effect upon beneficial insect populations.

The commenter supplied data which indicate that the effect of dicofol on snow scale is seasonal. These data show that dicofol can be used during the spring and fall without increasing snow scale, but that during the summer growers would need to supplement dicofol with scalicides in groves infested with snow scale. Although the Agency recognizes this seasonal variation effect, it does not alter the chlorobenzilate benefit analysis, because that analysis was based on the use of chlorobenzilate during the summer when growers could not use dicofol alone (Luttner, 1978a; Knapp, 1978b).

Secondly, the commenter [39 (30000/3D)] questioned the Agency's statements on the oncogenic effects of dicofol (Position Document 3, Appendix C). The Agency's statements on dicofol's oncogenicity were based on preliminary results of an NCI study in which dicofol reportedly induced hepatocellular carcinomas in male mice. This commenter questioned the validity of the dicofol bioassay as follows:

* * * according to the NCI Clearinghouse on Environmental Carcinogens, the stability of the sample of dicofol fed the animals in the NCI studies was not maintained throughout the study so that it is unclear what the animals were fed. Therefore, the Clearinghouse has indicated that the NCI studies prohibit drawing any conclusions concerning dicofol carcinogenicity.

The Agency's Carcinogen Assessment Group (CAG) did not agree that this problem invalidated the NCI study for several reasons. First, the NCI increased the amount of dicofol which they fed to the animals during the latter part of the study, perhaps to compensate for the degradation of the initial dose of the chemical. Second, the Agency has no information about the stability of this compound when it is actually applied to citrus crops; it is possible that decomposition of the compound during the NCI bioassay parallels that in the field. Thus, it is immaterial whether the male mice responded to the parent compound or its decomposition products since exposure to both is expected. Finally, participants in the Clearinghouse Meeting stated that hepatocellular carcinoma among treated mice was 74% in the high dose group and 44% in the low dose group, as compared to 25% in historic controls and 17% in experimental controls. The CAG believes that this is a statistically significant induction of hepatocellular carcinoma, and therefore sufficient to conclude that dicofol is carcinogenic in male mice (Albert, 1978).

b. *Hirsutella and Diflubenzuron.* One commenter [42 (30000/3D)] asked by the Agency had not evaluated two alternatives for chlorobenzilate (diflubenzuron and *Hirsutella*) which they termed "promising." The Agency reviewed these potential alternatives before issuing Position Document 3 (McWhorter, 1978d) and agrees that these are promising. However, neither diflubenzuron or *Hirsutella* is currently registered as a citrus miticide, and their effectiveness on citrus crops as well as the potential risks associated with these uses have not yet been fully evaluated.

3. *Need for Miticides.* Several commenters questioned the need for miticides, especially for the large percentage of citrus fruit which is destined for the process market. Two respondents disputed the Agency's position that mites need to be controlled because they affect fruit size, appearance, crop yield, and tree stock stamina (Position Document 3, p. 44). For example, one commenter [42 (30000/3D)] suggested that chlorobenzilate does not need to be used on citrus fruit which is to be processed, and that the Agency should have considered cancelling the use of chlorobenzilate on all citrus fruit intended for processing.

[1] This division of FDA became part of the EPA when the Agency was established in 1970.

[2] The BAT consisted of USDA and State extension and research personnel.

Another commenter [50 (30000/3)] asserted that mites affect the appearance of citrus fruit and that this is merely a cosmetic effect rather than a substantive effect such as a change in yield. The commenter concluded that the Agency's benefit analysis overestimated the economic benefit derived from the use of chlorobenzilate on citrus crops, leading the Agency to continue registrations of chlorobenzilate on citrus fruit rather than cancelling them. This commenter implied that it may not be necessary for growers to treat citrus crops for mites at all.

a. *Yield Effects of Rust Mite Damage.* One commenter [50 (30000/3)] noted, "One would expect citrus rust mite damage to be of less importance to the processor, as it affects only the appearance of the fruit." However, information available to the Agency contradicts the assertion that rust mite damage affects only the appearance of the fruit. Several researchers have evaluated the impact of citrus rust mites on citrus production and found that, in addition to harming the appearance of the fruit, citrus mites have other adverse effects upon both citrus trees and fruit, including lower yields due to increased fruit drop and decreased fruit size; leaf drop; damage to leaves and young shoots; and increased fruit transpiration rates both on the tree and when the fruit is in the marketing process (Yothers and Mason, 1930; Spencer and Osburn, 1950; Albrigo and McCoy, 1974; Yothers, 1918; Pratt, 1958). For example, a recent study showed that mite damage reduces tree longevity: of 4,692 Florida orange trees lost due to insect damage in 1977, 1,753 trees (or 36%) were lost due to rust mite damage (Doane Agricultural Service, Inc., 1978).

The most significant research to date on the nature and extent that yield is affected by citrus mites is that of Allen (1978a, 1978c) and Allen and Stamper (1978), which has become available since Position Document 3 was published. Allen was the first to use quantitative methods to determine the degree to which rust mites reduce yields by causing fruit to drop from the trees and by reducing fruit size given specific levels of mite infestation. Allen's fruit drop work has demonstrated that citrus fruit damaged by rust mites tends to lose water more rapidly than undamaged fruit, and damaged fruit also has a lower bonding force to the tree. Four different studies have shown that fruit which has been damaged by rust mites is more likely to drop from the tree prematurely than will undamaged fruit (Allen, 1978a).

Effects on fruit growth similar to those found by Allen were described by Tono et al. (1978). These authors found that the citrus rust mite reduced the diameter, volume, and weight of Satsuma mandarin oranges when compared to undamaged fruit. Allen condluded that, "since the data of Tono et al. (1978) for a different rust mite attacking a different citrus species is very similar to the present study, the effects of citrus rust mite on other citrus varieties are probably similar to that reported here" (Allen, 1978c).

Allen has very recently developed a simulation model to predict yield loss based on mite densities, control timing, and different control strategies (Allen, 1978c). Allen's recent data concerning the relationship between yield effects and the fruit surface area which is damaged by mites indicate that, in the absence of treatment for mites, growers can expect fruit surface area damage (russetting) ranging from a low of 10% to a high of 50%. Allen's new data for oranges and grapefruit show the following yield effects at these damage levels: [3]

| Surface area damage (pct) | Volume loss (pct) (includes drop plus size reduction) | Reduction insoluble solids (pct) |
|---|---|---|
| 10 (Low) | 4.38 | 3.53 |
| 30 (Med) | 13.61 | 11.00 |
| 50 (High) | 23.89 | 19.33 |

These volume loss data provide new support for the Agency's earlier estimates of 21.2% (oranges) and 25.3% (grapefruit) at the 50% damage level and 11.6% (oranges) and 14.0% (grapefruit) at the 30% damage level (Luttner, 1978c). Allen's new data also include figures on the reduction of soluble solids, an economic loss which was not known and therefore not included in the Agency's earlier analyses, and which indicates another benefit of controlling citrus mites.

To support his contention that mites damage only the appearance of citrus fruit, this commenter [50 (30000/3)] quoted several sources, including Griffiths and Thompson (1953), Reinking (1967), Simanton (1962), McCoy et al. (1967a), Ziegler and Wolfe (1975), Townsend (1976), and Olmert and Kenneth (1974). The Agency does not agree with his interpretation of the conclusions of some of these sources, while the results of others were taken out of context. In addition, one source did not deal with chlorobenzilate at all, while another was strictly a laboratory and not a field test.

Most importantly, the performance of chlorobenzilate was not evaluated in most of the studies cited. Further, the data presented by the commenter as Table 4 (reproduced on the following page) appear to be very misleading. "Significance" was apparently assigned in most instances by the commenter and not by the authorities who generated the data. The problems associated with using Griffiths and Thompson (1953), Reinking (1967), and Simanton (1962) as sources have already been discussed, and are discussed in detail in Ludvik (1978). The McCoy et al. (1967a) reference must not have been read correctly. These authors clearly show that on the average for a four-year period, yields measured as "mean pounds solids/year" were 3,986.2, 3,887.1, and 3,499.5 pounds for conventional, integrated, and no-spray programs, respectively. The first two did not differ significantly, but the third did differ significantly from the other two. The commenter cited 3,896 and 3,500 pounds as "NS" and thus ignored a major thrust of the research described, namely, comparison of a "complete" and an integrated spray program with a no-spray program. For purposes of this discussion, the Agency is primarily concerned with the Commenter's use and interpretation of the data, rather than with the data as generated and analyzed by the several authors.

The Agency concludes that there are yield effects associated with rust mite infestations. However, the benefit analysis is insensitive to the level of such damage, because no yield benefits were claimed for chlorobenzilate over substitute miticides which would be used to replace it.

[3] These data reflect mite damage on June 1 and harvest on April 1 for Valencia oranges; June 1 damage and March 1 harvest for grapefruit. Both situations are typical for Florida (Allen, 1979). Allen's analysis (for oranges) projects these relationships over a range of 1% to 80% surface area damage (0.5% to 42.3% volume loss, respectively.

NOTE: This table is reproduced from the submission of commenter 50 (30000/3).

TABLE 4

YIELDS OF CITRUS IN SPRAYED AND UNSPRAYED PLOTS

| State | Crop | Yield | | Significance 1/ | Source |
|---|---|---|---|---|---|
| | | Spray | No Spray | | |
| Florida | Valencia Oranges | 2.9 boxes/tree | 2.9 boxes/tree | NS | Griffiths & Thompson (1953) |
| Florida | Seedy Grapefruit | 10.0 ave. - 13.4 expct. ave. of boxes/tree | 8.7 Ave.-10.8 expct. ave. of boxes/tree | NS | Griffiths & Thompson (1953) |
| Texas | Oranges | 126 lbs/tree | 123 lbs/tree | NS | Reinking (1967) |
| Texas | Grapefruit | 372 lbs/tree | 285 lbs/tree | NS | Reinking (1967) |
| Florida | Oranges | 201 boxes/acre | 201 boxes/acre | NS | Simanton (1962) |
| Florida | Grapefruit | 307 boxes/acre | 245 boxes/acre | ? | Simanton (1962) |
| Florida | Tangerine | 310 boxes/acre | 310 boxes/acre | NS | Simanton (1962) |
| Florida | Oranges | 3,896 lbs solid/acre | 3,500 lbs solid/acre 2/ | NS | McCoy et al. (1976) 3/ |

1/ Mite infestation due to yield reduction.
2/ Lower yield caused by greasy spot fungus infestations.
3/ McCoy et al. (1976a).

[6560-01-M]

b. *Economic Importance of Russetting.* A commenter [50 (30000/3D)] also implied that miticides are unnecessary in citrus production, because there are no marketing incentives to avoid mite damage. Aside from the effects on yield, the russetting factor is economically important, because russetted fruit commands a lower price in the fresh market for citrus fruit; russetted fruit commands a lower price because American consumers prefer non-russetted citrus fruit, a preference that is reflected in the USDA grading system. These fresh market sales provide significant revenues to citrus growers in all States, and are especially important for certain crops in Arizona, California, and Texas, where volume sales of both oranges and grapefruit in the fresh market exceeded volume sales of these crops in the process market during 1977-1978 (U.S. Department of Agriculture, 1978). Therefore, growers plan to sell as much of their fruit as possible to the fresh market. However, because growers cannot predict during the growing season how much of their fruit they will be able to sell to the fresh market, they tend to treat their fruit with miticides in order to maximize their sales potential in the fresh market.

This commenter [50 (30000/3)] disagreed with the conclusion that bright, undamaged fruit command higher prices: "Another point that was missed is that russetted grapefruit sell for a premium price on some markets. All this information is in the literature."

The actual and complete quotation from Ziegler and Wolfe (1975) is:

"Russetted fruit is just as good to eat as bright fruit, and some markets even pay a premium for it, although it is unusually discounted somewhat for poor external appearance and may not keep as long." Ziegler and Wolfe (1975) did not cite references to support their statement, identify locations, or indicate the magnitude of sales or the percentage of the total market involved, yet this commenter presented their statement in a manner which suggested that a major segment of the citrus market had been ignored in the Agency's analysis. The Agency has since verified that such a market does exist. It is a limited local specialty market which, according to Wardowski (1978) accounted for the sale of 0.83%, 0.02%, and 0.03% of the fresh grapefruit, oranges, and tangerines, respectively, in Florida in 1976-1977. Wardowski (1978) also commented that "the contention [50 (30000/3)] that russetted grades of grapefruit command higher prices is seldom correct." He also said that, based on the *Annual Statistical Record, 1977-1978 Season*, by the Citrus Administrative Committee, the average prices for russetted grades of grapefruit for the 1977-1978 season are appreciably lower than for better looking fruit. There are occasional exceptions when russetted grades command higher prices, as for example the Indian River white seedless grapefruit sold during the week ending June 18, 1978. However, no one could sell those grades for premium prices on the season-long average; such a specialty market is very 'price elastic' [4], and an extra carload or two could well break the market (Wardowski, 1978).

In addition, commenters recognized that processors often pay less for marked fruit, even though one would think cosmetic appearance would be of little or no consequence to them. Internal quality is of greater importance to the processor than external appearance, but when the crop is large and the fresh fruit market slow, the processor tends to discount fruit for external quality even though the lower grade fruit is fully as satisfactory for his use.

The Agency concludes that russetted fruit is less valuable in the fresh market and even in the process market. Apart from any other losses in quantity or quality (e.g., reduction in soluble solids), russetting causes economic damage. It is economic damage to the grower if he receives a lower price for a crate of russetted fruit, regardless of whether he suffered a loss in yield, i.e., he got fewer crates from the grove.

4. *Value in IPM Programs.* Two commenters (40, 50 (30000/3D)] questioned the Agency's position that chlorobenzilate is an important component of IPM programs to control the citrus rust mite in citrus groves. As described in Position Document 3, the Agency's position is based in the demonstrated benefits of using integrated chemical and biological pest management (IPM) practices on citrus crops, as in Florida where chlorobenzilate is used to control rust mites in combination with parasitic wasps which were introduced to control the scale insects endogenous to Florida citrus groves. Initially, a parasitic wasp release program was instituted in Florida during the 1950's to control scale insect infestations, and this program established parasite populations which control purple and red scale throughout the entire State. In 1973, the University of Florida began a Federally-funded demonstration IPM program involving chlorobenzilate and the parasitic wasps. This program has shown growers throughout the State that using chlorobenzilate in IPM programs controls the rust mite without harming the parasitic wasp populations. Currently, biological scale control efforts are directed at release and establishment of a third wasp species to control snow scale (Brooks, 1977). Current data (Doane Agricultural Service, Inc., 1978)[5] which indicates that at least as much chlorobenzilate is now being used as was reported in the 1975 data on which the Benefits Analysis was based, reflect the success of this IPM program.

An important dimension of IPM in Florida has been the reduced need for chemical control of scale insects. Prior to the introduction of two *Aphytis* species, purple and Florida red scales were ranked as the first and fourth most important pests of Florida citrus, respectively (Thompson, 1955). However, ". . . spectacular successes of biological control of Florida red scale, *Chrysomphalus aonidum* (L.), and purple scale, *Lepidosaphes beckii* (Newm.), have reduced the need for multiple applications of organic phosphate insecticides" (McCoy et al., 1976b). The program to establish scale parasites was so successful that, at present, both insects are considered to be minor pests (Brooks, 1977). Both red and purple scale can still be found at very low levels in most Florida citrus groves and are generally only serious where parasite development has been retarded (Brooks, 1977). The maintenance of scale parasite populations represents a very significant IPM consideration throughout Florida's citrus-growing areas.

In California, chlorobenzilate is by far the most effective material for control of citrus bud mite on lemons. It is estimated that, without chlorobenzilate, one petroleum spray would be required on all of the southern California lemon acreage, and two petroleum oil sprays would be required on two-thirds of the acreage each year. As a consequence of using chlorobenzilate, only a fraction of this acreage needs to be treated each year. The use of chlorobenzilate in Florida and Texas, primarily to control the citrus rust mite, has been one of the key factors enabling growers in these States to significantly reduce the total number of pesticide treatments applied each year. Chlorobenzilate provides excellent rust mite control without the phytotoxic properties of petroleum oil during periods of stress to the trees and with little or none of the reductions in populations of important beneficial insects which the nonselective alternatives cause.

5. *Variability of Actual Benefits.* In the previous sections, a number of commenters raised issues relating to the Agency's analysis of benefits. While each of these issues were discussed individually, as a group they implied that the Agency had overestimated the economic impact of cancelling chlorobenzilate. This general concern is discussed below.

The Benefit Analysis projected that cancelling the use of chlorobenzilate on citrus crops would cost approximately $13.1 million the first year after cancellation and increase to $57.6 million by the fifth year. These projections were based on the recent use patterns for chlorobenzilate, the dynamics and interelationships between pests and beneficial insects in citrus groves, and the impacts which might reasonably be expected to occur if substitute pesticides were used to control the rust mite. Although Position Document 3 stated that these projections are based on a number of variables and assumptions and that the projected cost totals are maximum values, the commenters have apparently interpreted the projections as precise impacts. This misunderstanding might have been avoided if the discussion had indicated a range of possible impacts rather than reporting point estimates.

It is possible that in any given year the loss of chlorobenzilate on citrus fruit would result in no economic impacts other than the higher replacement costs for alternative miticides (about $3 million per year). However, this could occur only if infestations of scale insects did not materialize in the absence of scale parasites, thus making it unnecessary to treat the groves to control scale insects. In view of the fact that purple and red scale now exist at generally sub-economic levels throughout the State (and that snow scale also infest about 75% of Florida's citrus acreage), and given the toxicity of certain of the major alternative miticides to scale parasites, the Agency considers the likelihood of such an occurrence to be extremely unlikely. It is inappropriate to assume a constant need for additional scale control treatments on all of the Florida citrus acreage, since scale populations could reasonably be expected to vary by year as well as by area. The same argument also ap-

[4] The price is very sensitive to changes in supply.

[5] This new data, which has just become available to the Agency, indicates that more chlorobenzilate is now being used. This could increase both the risks and benefits associated with the citrus uses of chlorobenzilate. However, the Agency did not receive this information in time to evaluate it and correspondingly revise both the risk and benefits estimates.

plies to the projected need for added mite control treatments on additional acres of lemons in California if chlorobenzilate is unavailable.

The Agency has reviewed the incidence of economic infestations of red and purple scale in the citrus-growing States during 1975 and more recent years (Doane Agricultural Service, Inc., 1976, 1978) and the incidence of use of multiple applications of organophosphates which are harmful to scale insect predators and has found that a relationship appears to exist. The more such chemicals are used (including insecticides as well as miticides), the more treatments will be required for red and purple and unspecified scale insect problems.

There is no precise methodology or logic which the Agency can use to assign probabilities to the many outcomes which could ensue if chlorobenzilate were cancelled. Keeping in mind that red and purple scale insects are presently an economic problem for a number of growers and that low levels of infestation exist on most of the acreage, it is reasonable to project that most of the citrus acreage could easily be infested by red and purple scales which would require treatment if the existing parasites were killed because growers were using miticides other than chlorobenzilate.

In view of the numerous biological, environmental, and economic factors involved in projecting economic impacts, the projection of such impacts is necessarily judgmental. The Agency's conclusion is that, quite clearly, the upper limit of economic impacts on citrus could occur in a given year ($57 million). In any given year, the particular combination of environmental and economic variables will cause this projection to vary. While the Agency recognizes the probabilistic nature of the conclusions of the benefit analysis, it is confident that the economic benefits of using chlorobenzilate on citrus crops are substantial and that the range of variability in the projected impact of cancelling the citrus uses of chlorobenzilate would not be of sufficient magnitude to change the Agency's regulatory decision.

### C. COMMENTS RELATING TO REGULATORY OPTIONS

1. *Non-Citrus Uses.* In Position Document 3, the Agency recommended cancelling all non-citrus uses of chlorobenzilate, because: 1) chlorobenzilate poses a risk of cancer and adverse testicular effects to humans, and 2) no benefits would be lost, since effective alternatives are registered for each of the non-citrus uses of chlorobenzilate. In some cases these alternatives are less expensive than chlorobenzilate and achieve comparable levels of control.

The Secretary of Agriculture [36 (30000/3)] recommended that the Agency continue the registrations for chlorobenzilate use on cherries, walnuts, melons, almonds, cotton, certain ornamentals, and outdoor areas.

The Secretary stated:

"In view of the relatively small amount of chlorobenzilate used on these crops and, thus, the correspondingly small risk associated with these uses, the Department recommends that these registrations be continued while biological and economic data are obtained in order to better determine the complete risk/benefit situation. A requirement for accomplishing this during the same 18-month period allowed for collecting additional exposure data on the citrus uses should be included in the final determination.

The SAP also recommended that the Agency continue all non-citrus uses. Specifically, the Panel stated:

"The Scientific Advisory Panel believes the registration for chlorobenzilate on non-citrus crops and ornamentals should continue on the same basis as for citrus crops. In this regard, the proposed studies concerning residues in food crops, applicator exposure, aerial application exposure, etc., required in Option F for citrus crops should also be required for non-citrus crops. The Scientific Advisory Panel believes the continued use of chlorobenzilate on non-citrus crops is justified on the basis of the fact that alternative pesticides may pose a greater potential health threat than chlorobenzilate."

Another commenter [42 (30000/3D)] agreed with the Agency's decision to cancel all non-citrus uses, but disagreed with the decision to allow citrus uses to continue.

The recommendation to cancel the non-citrus uses of chlorobenzilate was based in part on the results of USDA's questionnaire to all State Pesticide Impact Assessment Liaison Coordinators concerning the value of these uses. Except for one comment that chlorobenzilate is important in controlling clover mites around buildings (Allen, George E., 1978), that questionnaire elicited no information on benefits of the non-citrus uses. Therefore, the Agency considered this a confirmation of its preliminary conclusion that no appreciable benefits were associated with these uses.

It is true, as the USDA noted, that a relatively small amount of chlorobenzilate is used on these crops, and that there is a correspondingly small risk. However, neither the USDA nor the SAP submitted any additional information to suggest that there are benefits to be gained from these uses of chlorobenzilate or that the benefits exceed the risk. Moreover, many alternative pesticides are available for the non-citrus uses, and, based upon currently available toxicology data, several appear to be less hazardous than chlorobenzilate. These alternatives are listed in Table 14 of Position Document 3. Therefore, neither registrants, the USDA, nor the SAP have provided information to justify the risk associated with the continued use of chlorobenzilate on these non-citrus crops.

2. *Use of Chlorobenzilate on Citrus Crops in Arizona.* Although the Agency decided to continue registrations of chlorobenzilate use on citrus crops in Florida, Texas, and California (with amended terms and conditions of registration, including a requirement to submit specific exposure data within 18 months), the Agency recommended that chlorobenzilate use be cancelled on citrus crops in Arizona.

The Secretary of Agriculture and the SAP [36, 45 (30000/3)] both recommended that chlorobenzilate registrations be continued for citrus crops in Arizona. The SAP stated that all States should be permitted to use chlorobenzilate on citrus fruit, because the data which the Agency presented was inadequate to justify excluding any State. The USDA explained that, "The benefits of chlorobenzilate use in (Arizona) citrus production are greater than originally perceived," and, "A benefit analysis for Arizona citrus should be developed and evaluated." In addition, several other commenters [40, 46, 38, 41, 47, 48, 44, and 51 (30000/3)] objected to cancelling chlorobenzilate use on citrus fruit in Arizona, but generally provided no data supporting these opinions.

In 1976, the USDA surveyed various pesticide officials in citrus-producing States, including Arizona, to determine their need for chlorobenzilate, but Arizona pesticide officials did not respond. USDA supplied the results of that survey (Riley, 1976) to the Agency. Since Arizona had provided no information, the Agency concluded in Position Document 3 that chlorobenzilate was not regarded as useful or important by Arizona.

After discussing this issue with the SAP, the Agency requested additional data from the USDA that might support their claim that chlorobenzilate is needed in Arizona (Boyd, 1978a). As a result, officials from the University of Arizona [47, 48 (30000/3)] provided the Agency with information whch included the results of field trials on the comparative usefulness of various miticides, statements on possible mite resistance to dicofol, and data on reduction of beneficial arthropod populations due to miticides other than chlorobenzilate. Further, the University of Arizona noted that an acarologist and a citrus entomologist are developing integrated control programs for Arizona which include chlorobenzilate.

As stated in Position Document 3, the use of alternatives to chlorobenzilate may disrupt IPM strategies in Arizona. The Agency observed that although the extent of natural controls is unknown, the generic selectivity of chlorobenzilate would make its use compatible with the endemic arthropod parasites and predators in Arizona.

The possible disruption of IPM strategies, when considered with Arizona's recent activities, stated intentions, and willingness to research and develop integrated programs which use chlorobenzilate in conjunction with existing biological controls, justifies the continued availability of chlorobenzilate for use on citrus crops in Arizona.

In view of the information now available, the Agency has determined that the risk of using chlorobenzilate on citrus crops in Arizona is outweighed by the associated benefits. The registration of chlorobenzilate for use in Arizona is therefore continued under the same terms and conditions of registration specified for California, Florida, and Texas.

3. *Use of Citrus Pulp As Cattle Feed.* One commenter [42 (30000/3D)] disagreed with the Agency's decision to allow pulp from citrus fruit which had been treated with chlorobenzilate to continue to be used as cattle feed, arguing that the "pulp feed use is hazardous exposure and should not be continued until there are better data." This commenter took issue with the Agency's position that prohibiting chlorobenzilate residues in citrus pulp would amount to a *de facto* cancellation. It is logical to assume that if the processors could not sell pulp from chlorobenzilate-treated citrus fruit, they would refuse to accept fruit treated with chlorobenzilate. Since over 80% of Florida citrus fruit is processed, if growers stopped using chlorobenzilate for this reason, a prohibition on the sale of chlorobenzilate-treated pulp may amount to a *de facto* cancellation.

The studies which the Agency is requiring will determine whether or not there are significant chlorobenzilate residues in meat and milk as a result of feeding pulp from treated fruit to the cattle. If significant resi-

dues are found, the Agency will re-evaluate its position on the pulp feed issue.

This group [42 (30000/3D)] also noted, "There is no tolerance set for chlorobenzilate residues in citrus pulp."

There are currently chlorobenzilate tolerances on citrus fruit at 5 ppm and on meat, fat, and meat by-products of cattle and sheep at 0.5 ppm. An additional tolerance would be required on pulp used as animal feed only if the concentration of chlorobenzilate in citrus pulp exceeds the 5 ppm permitted on citrus fruit. This can be determined when the required residue data are submitted.

At the present time, there is no tolerance for chlorobenzilate in milk. Therefor, any detectable residue of chlorobenzilate would make the milk subject to seizure by the Food and Drug Administration (FDA). Such detectable residues (> 0.01 ppm) are not likely, based on the current data (Reed, 1978), but the results of the required residue studies should clarify this. The citrus fractionation study and the citrus by-product monitoring data which the Ageny is requiring will also enable the Agency to more realistically and accurately assess the potential amount of dietary exposure from citrus oil, as discussed in Section II (A)(2)(c), as well as other sources. In any case, seizure at levels above detection level is as conservative and safe a posture as can be taken, short of prohibiting feeding of treated pulp. Maintaining the status quo is as effective in this case as establishing a tolerance.

4. *Additional Studies.* As a condition of continued registration, the Agency will require additional studies to be performed within an 18-month period. One commenter [42 (30000/3D)] argued that the Agency should require the results of the following studies to be submitted before making a regulatory decision: exposure studies on citrus pickers and applicators; residue monitoring studies on citrus pulp, milk, and meat; and studies on metabolism, degradation, and environmental fate. This commenter noted that the exposure studies which the Agency will require within 18 months "could indicate a very significant adverse human reproductive effect." Therefore, the results of these studies "should precede the decision to continue uses," instead of following it.

The RPAR process is not intended to fill all data gaps which are found to occur with respect to a chemical. However, the Agency may require registrants to conduct studies on metabolism, degration, and persistence or other effects as a condition of registration. In the case of chlorobenzilate, the Agency will require the exposure studies and residue monitoring studies described in Position Document 3 as a condition of continued registration and will use the results of these studies to reassess the risk associated with using chlorobenzilate.

This commenter also objected to the fact that the registrant(s) rather than someone else will conduct the exposure studies which the Agency is requiring. FIFRA gives the Agency authority to require registrants to conduct all studies in support of pesticide registrations. Although the Agency may itself conduct studies to develop pesticide hazard and exposure data, data of this type is generally provided by registrants.

This commenter also objected that data on chlorobenzilate residues in citrus pulp as well as the plans and protocols for the new studies which the Agency is requiring were all secret. Most of the data on which the analyses in Position Documents 3 and 4 are based is available to the public in the position documents themselves, in the references, or in other supporting documents in the official RPAR file on chlorobenzilate. In addition, copies of attachments to these position documents which were not published with the notice of determination are available in the public file that the Special Pesticide Review Division maintains for each RPAR pesticide. Information protected from disclosure pursuant to Section 10 of FIFRA cannot be provided.

The SAP [45 (30000/3)] recommended that, "Due to the lack of information on the potential adverse effects of chlorobenzilate on human reproduction, we recommend the following studies:

(a) The examination of sperm counts in a selected population of chlorobenzilate applicators, and

(b) A three-generation reproductive study in rats at sufficient dose levels to allow the determination of a no-adverse-effect level of chlorobenzilate on reproduction in that species. This study should be carried out using the protocol currently described in the proposal EPA guidelines for risk assessment of FIFRA chemicals."

The Agency agrees with the SAP that a three-generation reproduction study would be worthwhile, and will require the registrants to conduct such a study according to the protocol described in the proposed EPA guidelines for hazard assessment (43 FR 163:37384–37385, August 22, 1978).

The SAP's recommendation that sperm counts in applicators be examined will be considered again when data from the animal studies become available (Gardner, 1979). If data from the reproduction study suggest that human applicators should also be studied, applicator sperm counts may then be required.

5. *Reducing Occupational Risks*—a. *Risk to Applicators.* The Agency found in Position Document 3 that spray applicators are the population at greatest risk as a result of applying chlorobenzilate on citrus fruit. The Agency proposed steps to reduce their exposure by amending the terms and conditions of registration so that chlorobenzilate may be applied only by certified applicators. Further, ground applicators would have to use either protective clothing and a respirator or a suitably-equipped enclosed cab. In addition, as a condition of registration, the Agency is requiring that the registrant submit additional data which can be used to further assess exposure to applicators.

The Secretary of Agriculture and several other respondents commented on the Agency's recommendations to reduce the risk to applicators. The USDA [36 (30000/3)] offered to assist the Agency and the registrants in developing "research protocols for obtaining the necessary dermal and inhalation data on exposure to chlorobenzilate" as well as in evaluating "alternative methods of reducing exposure." Although the final specifications for all required studies must be approved by the EPA, the USDA's assistance will be welcomed in developing studies and evaluating alternative protective measures.

The Secretary of Agriculture agreed with the Agency's decision to allow chlorobenzilate to be applied by certified applicators only, but disagreed with the requirement to specify clothing type or respirator requirements on the label. The Agency originally specified that protective clothing should be made of "jersey", which was intended to describe any finely-woven fabric. The Agency will clarify its clothing requirement as follows: applicators must wear one-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the USDA/EPA *Guide for Commercial Applicators*, which was cited by USDA. In addition, the Agency will continue to require that applicators wear heavy-duty fabric work gloves and a wide-brimmed hat when applying chlorobenzilate.

Under its requirements for clothing and equipment for applicators, the Agency also stated that, "Any article which has become contaminated must be replaced" (Position Document 3, Appendix D). A commenter [40 (30000/3D)] recommended that this be changed to, "Any article which has become contaminated must be cleaned before reusing."

The Agency will accept this modification; however, clothing worn when applying chlorobenzilate should not be worn again until it has been laundered separately, using a strong detergent and liquid chlorine bleach. If clothing is drenched or exposed to concentrated pesticide, it should be buried or burned.

The Secretary of Agriculture [36 (30000/3)] suggested that the Agency simply encourage ground applicators to wear respirators instead of requiring this on the label. Several other commenters [37, 40 (30000/3D); 43, 47 (30000/3)] also contended that the respirator requirement is impractical or unwarranted and should be deleted from the proposed measures.

While the Agency recognizes that wearing a respirator poses some discomfort and entails frequent maintenance, the respirator provides a significant amount of protection to ground applicators as does the protective clothing. In view of the many comments on this issue, the Agency has recalculated its ground applicator exposure estimates. The revised exposure estimates for ground applicators (Severn, 1978) are based on exposure to forearms, hands, and face (15.8% of the total body surface). Covering the forearms and hands would reduce dermal exposure from between 12 and 40 mg/day, as stated in Position Document 3, to between 4 and 10 mg/day. Face-piece respirators would effectively eliminate exposure by inhalation, estimated at 1 mg/day, and further reduce dermal exposure to the face by 1–3 mg/day. Thus, the total exposure could be reduced to between 2 and 6 mg/day (Severn, 1978).

Using protective clothing and respirators will reduce the estimated lifetime cancer risk to applicators from its current level (400 to 1,400 in one million) to between 65 and 190 in one million. There would also be a greater margin of safety [5] (371 to 1,884 as opposed to 55 to 291 without protective clothing and respirators) from testicular effects (Gardner, 1978). The Agency has concluded that this reduction in risk would tend to outweigh both the minimal cost for the protective clothing and the respirators and any potential discomfort which applicators may encounter during the 18-month period in which the exposure studies are being conducted. Therefore, until the required applicator exposure data are submit-

[5] The margin of safety is the ratio of the no-observed-effect level in test animals to the projected human exposure and is based on the assumption that chlorobenzilate irreversibly affects testes, which represents the worst possible situation.

ted and evaluated, the Agency will require applicators to wear protective clothing, as described in this document, and to use a respirator, as described in Appendix D of Position Document 3. If the new exposure data indicate a lower level of risk, the Agency will reconsider the need for applicators to wear respirators. In addition to these requirements, the general and handling precautions described in Appendix D of Position Document 3 are required.

One commenter [46 (30000/3)], suggested that the tractor canopies which are currently in use reduce applicator exposure more than respirators could. However, the commenter provided no specific data to support this claim, and the Agency cannot assume that the canopy, although already in widespread use, could be used in place of respirators as a means of protection for ground applicators. The ground applicator study will allow the Agency to assess the actual exposure these applicators currently receive and revise its regulatory measures, if indicated.

b. *Risk to Pickers.* Citrus pickers are also occupationally exposed to chlorobenzilate, but the available data was insufficient to estimate their exposure and potential risk. As described in the exposure analysis (Severn, 1978), various data on dislodgable chlorobenzilate residues are available, but this data is not adequate to determine the extent to which pickers absorb such pesticide residues. Since the pickers work in the groves after the pesticide is applied, the Agency assumed that they would be exposed to less chlorobenzilate than the applicators, but the available data does not permit a risk assessment for Florida citrus pickers. In order to obtain the data needed for a risk estimate and perhaps subsequent regulatory action, the Agency is requiring studies to determine whether and to what extent dislodgable chlorobenzilate residues may adhere to pickers. In addition, the Agency will require studies which define the degradation rate of chlorobenzilate under field conditions.

One commenter [42 (30000/3D)] recommended that the Agency require protective measures for citrus pickers during the 18-month data-gathering period, but provided no data to support this recommendation. The Agency did not recommend interim regulatory measures pending new data development because, as indicated above, the data needed for risk assessment was not available.

6. *Comparison of Options D and F.* One group [42 (30000/3D)] disagreed with the Agency's selection of Option F. This group contended that the Agency should have selected Option D, which would have limited chlorobenzilate's availability to five years. It felt that this option would reduce potential lifetime effects, encourage technological innovation, and "reflect a conclusion" that the risks associated with using chlorobenzilate are unacceptable if continued indefinitely.

The Agency feels its decision to request relevant information within 18 months provides an even greater degree of safety than Option D. If the Agency has underestimated the risk, it can take appropriate regulatory action at the end of 18 months when the new information is available. Furthermore, the course being pursued by the Agency in no way discourages development of these alternatives.

This commenter also claimed that rejecting Option D "is contrary to the most recent official Agency actions," particularly the decisions on chlordane/heptachlor and Mirex, where the Agency allowed a period of time in which to develop alternative pest control technologies. The Agency makes every effort to reach informed decisions on each pesticide that it regulates. Because each pesticide may pose unique environmental problems as well as benefits, the Agency's decisions will vary with each particular situation. It is intended that each decision will reflect a balanced consideration of both the specific risks and specific benefits involved. As explained on page 19, alternatives for chlorobenzilate are being developed. The primary difference between these decisions is that the Agency did not view the risk from chlorobenzilate in comparison to its benefits as being as great as the risk from chlordane/heptachlor or Mirex, in comparison to the benefits of those pesticides.

This commenter [42 (30000/3D)] also noted that,

The Agency's selection of Option F is also inexplicable in view of its conclusion that no additional costs will be imposed on consumers unless cancellation results in significant reductions in yield or fruit grade. Due to excess production, stability of the industry and no projection of yield quality effects, growers would absorb any loss (Position Document 3, p. 65).

The Agency does have a mandate to be concerned about grower-level effects as well as consumer effects. This issue is discussed in the "Interim Administrative Procedures for Regulatory Decisions Involving Suspected Carcinogens" (41 FR 102:21403–405, May 25, 1976) and also presented as Appendix I(B) of the May, 1977 "Chlorobenzilate Preliminary Benefit Analysis."

## III. Conclusions

After reviewing comments from the Secretary of Agriculture, the Scientific Advisory Panel, and others who commented on the Agency's findings and recommendations concerning chlorobenzilate as set forth in Position Document 3, the Agency has decided to implement Option F, as set forth on page 87 of Position Document 3, with the following modifications:

### *OPTION F*

**Continue Registration of Chlorobenzilate Use on Citrus in Florida, Texas, California, and Arizona.*

The same terms and conditions of of registration are now required for Arizona as those for California, Florida, and Texas.

**Amend the Terms and Conditions of Registration*

The Agency will modify its requirements for applicator clothing and equipment in two ways. Where the Agency originally specified that protective clothing should be made of "jersey", the clothing requirement will be changed to one-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the *USDA/EPA Guide for Commercial Applicators.*

The Agency has also accepted modifications in this section regarding contaminated clothing. This requirement will now read, "Any article which has been worn while applying chlorobenzilate must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be buried or burned."

All other requirements for applicator clothing and equipment remain as stated in Position Document 3.

**Require That Identified Exposure Data Be Submitted to EPA in 18 Months; Reevaluate the Use on Citrus After Additional Exposure Data Becomes Available*

In addition to the exposure data required in Position Document 3, a three-generation reproduction study will also be required during the 18-month period. The study is to be conducted according to the protocol described in the proposed EPA guidelines for risk assessment (43 FR 163:37384-37385, August 22, 1978).

**Cancel All Other Uses*

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APPENDIX A.—USDA AND SAP COMMENTS

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
*Washington, D.C., August 2, 1978.*

MR. EDWIN L. JOHNSON (WH-566),
*Deputy Assistant Administrator for Pesticide Programs, U.S. Environmental Protection Agency, Washington, D.C.*

DEAR MR. JOHNSON: This is the United States Department of Agriculture's response to the Environmental Protection Agency's (EPA) Notice of Determination, pursuant to 40 CFR 162.11(a)(5), concluding the Rebuttable Presumption Against Registration (RPAR) on chlorobenzilate, and EPA's proposed intent to cancel or modify the terms and conditions of registration, pursuant to Section 6(b)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The notice, received on July 3, 1978, indicates EPA is proposing to (a) cancel certain uses of chlorobenzilate; and (b) retain major uses on citrus provided that appropriate changes in labeling are implemented by the registrants.

The U.S. Department of Agriculture and State cooperators, under the National Agricultural Pesticide Impact Assessment Program (NAPIAP), have been pleased to interact with EPA in developing information materials upon which the proposed EPA regulatory action is based. We reached agree-

ment on many important chlorobenzilate issues. Further, we are dedicated to mutual resolution of problems involving actual health risks to the consumer or farm workers. In many instances, the data base needed to accurately estimate potential risks of chlorobenzilate use is limited or not available, and we agree that better information must be obtained as soon as possible. We concur that chlorobenzilate should be classified as a restricted use pesticide and, thus, applied only by or under the supervision of a certified applicator. The issues of concern to the Department relative to the regulatory actions proposed in the Notice of Determination and our recommendations follow:

1. *Citrus uses:* The USDA-State-EPA chlorobenzilate assessment team reached agreement on the benefits of chlorobenzilate use on citrus in Florida, Texas and California. However, recent developments in Arizona indicate that the benefits of chlorobenzilate use in citrus production are greater than originally perceived. Arizona citrus producers have experienced difficulties with the use of the principal miticides that are being used in place of chlorobenzilate. Resistance is developing in some areas and some of these materials cannot be used when temperatures exceed 90 degrees F. In addition, toxicity to bees and other beneficial organisms make them less appropriate for use in integrated pest management programs than chlorobenzilate.

*Recommendation:* The use of chlorobenzilate on citrus in Arizona, which involves only a small amount of additional material (p. 3– of PD #3), should be continued under the same terms as for Florida, Texas and California. A benefit analysis for Arizona citrus should be developed and evaluated. A requirement for accomplishing this should be included in the final registration determination.

2. *Noncitrus uses:* In September 1977, the Department surveyed NAPIAP State Liaison Representatives to determine the importance of the noncitrus uses of chlorobenzilate. At that time, it appeared that adequate alternative miticides were available for the noncitrus uses of chlorobenzilate. In July 1978, State Liaison Representatives were recontacted to assure that all relevant and recent information is being considered in the decisionmaking process. They indicated the following concerns: More serious resistance to alternative materia;s possible loss of alternative pesticides through regulatory action or other means; and not having available miticides with the unique attributes of chlorobenzilate for developing effective integrated pest management systems.

The Department concurs with this reassessment by the State Liaison Representatives and believes continued use of chlorobenzilate for mite control is potentially critical for the following commodities: cherries, walnuts, melons, almonds, cotton, certain ornamental and other outdoor uses. We believe it is desirable to retain these registered uses of chlorobenzilate. We will provide detailed information on the importance of chlorobenzilate for these commodities within the same time frame provided for collecting citrus use exposure data. This action will also make it possible for research and extension workers to continue the evaluation of the most effective and compatible IPM systems for these specialty crops.

*Recommendation:* In view of the relatively small amount of chlorobenzilate used on these crops and, thus, the correspondingly small risk associated with these uses, the Department recommends that these registrations be continued while biological and economic data are obtained in order to better determine the complete risk/benefit situation. A requirement for accomplishing this during the same 18-month period allowed for collecting additional exposure data on the citrus uses should be included in the final determination.

3. *Occupational Exposure:* No specific data are available on applicator or agricultural worker exposure to chlorobenzilate. The Department agrees that 18 months are needed to collect adequate exposure information on chlorobenzilate.

The Department agrees with the need for protective clothing but believes that the specification of a one piece "Jersey" jumpsuit could pose availability problems. The Department does not concur with the requirement of a face piece respirator because this places an unreasonable burden on the applicator. Under hot and humid climatic conditions occurring in citrus-producing areas, the wearing of a face piece respirator is extremely uncomfortable and has caused breathing difficulties and chest pains for the operator. Aggravation of existing health problems or heat prostration also could occur. This may prompt an applicator to disregard the requirement or use the respirator intermittently, causing contamination of the respirator which could actually increase exposure. Data presented in Position Document 3 indicates that dermal exposure is significantly more important than inhalation as a route for applicator exposure (p. 30). Thus, protective clothing is a far more important factor in reducing applicator exposure than is the face piece respirator.

*Recommendation:* The Department recommends that the USDA-State-EPA chlorobenzilate assessment team meet with other employees of EPA and the registrants to assist in developing research protocols for obtaining the necessary dermal and inhalation data to fully assess applicator and field worker exposure to chlorobenzilate. This should include evaluation of alternative methods of reducing exposure. The Department recommends that chlorobenzilate be classified as a restricted-use pesticide to be applied by or under the supervision of certified applicators, without further specification on the label of clothing type or respirator requirements. We suggest that label wording be developed to encourage the use of a respirator but that it not be made a requirement for permitted use. In addition, we suggest the wording found on page 5-2 of *A Guide for Commercial Applicators*, USDA/EPA be used to specify protective clothing.

4. *Dietary Exposure:* The dietary exposures presented in Position Document 3 are theoretical exposures and do not reflect actual dietary exposures to chlorobenzilate. FDA residue monotoring programs reflect a very small percentage of total samples that contain chlorobenzilate. Of the 6-8,000 samples analyzed annually, approximately 0.12% contained chlorobenzilate residues most of which were reported at trace residue levels of less than 0.1 ppm. EPA assumed that all citrus and nut crops treated with chlorobenzilate contain the analytical detection sensitivity level of 0.1 ppm even though there were no detectable residues in most edible portions of these foods (p. 25). For apples and pears a residue of 5 ppm was assumed (the established tolerance) solely because a portion of these fruits are eaten as fresh, unpeeled produce. No reference is made as to whether residue tests were conducted for these commodities. In determining chlorobenzilate ingestion through milk for the Florida population it was assumed 100 percent of the milk came from cows fed citrus-pulp. No data were presented on the quantity of citrus pulp produced annually or the amount contained in the animal rations. It seems highly unlikely that all dairy cows in Florida would be fed citrus pulp on a continuing basis. Even if this is the case, it is highly questionable that residue levels would be as high as those assumed in the report.

To the extent EPA assumed higher residues than actually exist, the risks based on dietary exposure to chlorobenzilate are too high. Currently, a sensitivity level of 0.01 ppm is obtainable and is being used by FDA and CIBA-GEIGY as indicated in the assessment team's September 1977 letter to EPA. It is our view that these theoretical exposure estimates overstate the possible risk from the continued use of chlorobenzilate beyond a reasonable margin of safety.

*Recommendation:* The Department recommends that EPA recalculate the estimates based on obtainable analytical sensitivity. In addition, these theoretical calculations should be replaced with actual exposure data as it becomes available. The frequency of positive chlorobenzilate residue traces should also be taken into account in calculating theoretical exposure levels.

We are confident EPA will give favorable consideration to these suggestions and recommendations in developing the final chlorobenzilate registration determinations. The opportunity to have cooperated on this important agricultural matter is very much appreciated by us as well as the whole agricultural community. Please let us know if you need any additional information.

Sincerely,

BOB BERGLAND,
*Secretary.*

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF TOXIC SUBSTANCES
WASHINGTON, D.C., *August 17, 1978.*

To: Deputy Assistant Admnistrator for Pesticide Programs (TS-766).
From: Dr. H. Wade Fowler, Jr., Executive Secretary, FIFRA Scientific Advisory Panel (TS-766).
Subject: Review of Section 6(b) Action on Chlorobenzilate.

The FIFRA Scientific Advisory Panel has completed review of the Notice of Determination concluding the RPAR on chlorobenzilate and associated regulatory action under consideration by the Agency pursuant to Section 6(b) of FIFRA. Attached is a report of findings by the Panel.

The Panel waives all legal time constraints and agrees that EPA should implement appropriate regulatory action on chlorobenzilate as soon as possible.

Enclosure: Report.

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA) SCIENTIFIC ADVISORY PANEL

REVIEW OF NOTICE OF DETERMINATION CONCLUDING THE RPAR ON CHLOROBENZILATE

The FIFRA Scientific Advisory Panel completed review of documents outlining

plans by the Environmental Protection Agency to conclude the Rebuttable Presumption Against Registration (RPAR) on chlorobenzilate and for initiation of a combination of regulatory actions under the provisions of Section 6(b) of FIFRA, as amended. The review was completed in an open meeting held in Arlington, Virginia, on August 10, 1978.

Maximum public participation has been encouraged at all meetings of the Panel. In respect to formal review of the Agency position on chlorobenzilate, a FEDERAL REGISTER Notice announcing the meeting was published on July 25, 1978. Discussions relative to potential regulatory action by the Agency on chlorobenzilate were also held in meetings of the Panel in Miami, Florida, during May 25-26, 1978, (FEDERAL REGISTER Notice dated May 5, 1978), and Arlington, Virginia, on June 14, 1978, (FEDERAL REGISTER Notice dated May 26, 1978). In addition to public notices, telephonic calls and special mailings were sent to the general public who had previously expressed an interest in activities of the Panel. Written statements relative to regulatory action on chlorobenzilate were received over a period of several months from the following sources: CIBA-GEIGY Corporation (May 26 and June 22, 1978), United States Department of Agricultire (USDA), Florida Citrus Mutual (two submissions on July 3, 1978), Rohm and Haas Company, and the University of Arizona. Dr. C. Cueto of the National Cancer Institute (NCI) presented an overview of the results of a recently released NCI report on bioassay of chlorobenzilate for possible carcinogenicity. In addition, oral comments were received from EPA staff, USDA staff, Dr. Jim Griffiths of the Florida Citrus Mutual, Dr. Joseph L. Knapp of the University of Florida, members of the pesticide indutsry, and the general public.

In consideration of all matters brought out during Panel meetings, matters detailed in written statements, and careful study of all documents submitted by the Agency, the Panel submits the following report on chlorobenzilate:

The FIFRA Scientific Advisory Panel would like to compliment Dr. Wells, Mr. Boyd, and others of the Special Pesticide Review Division and technical support team (Working Group) on the quality of the position document on chlorobenzilate. In addition, we believe the regulatory option chosen by the Agency generally reflects a proper balance between economic considerations, implied health risks from exposure to chlorobenzilate and the availability of alternative pesticides.

The Scientific Advisory Panel is of the opinion the data supporting the consideration of chlorobenzilate as a potential carcinogenic chemical in man is weak. We feel the lack of a positive response in rats, and the weaknesses inherent in the Innes study leaves the NCI study as the only well documented evidence of an oncogenic potential for chlorobenzilate in man.

In spite of the weakness in the data suggesting an oncogenic potential in man, the Scientific Advisory Panel believes it is prudent to reduce the human exposure to chlorobenzilate to the extent feasible after due consideration of the economic aspects of this action and the availability of alternative pesticides.

The Scientific Advisory Panel believes too little attention was paid to the potential adverse effects of chlorobenzilate on human reproduction. The Scientific Advisory Panel considers the potential adverse effect on reproduction in humans to be as important an issue as the potential oncogenicity of chlorobenzilate. The Scientific Advisory Panel recognizes that the Agency and other interested parties only became aware of reproductive effects as a potential trigger late in the development of the decision document. Therefore, there appears to be some justification for the incomplete nature of the decision document regarding potential reproductive effects.

In regard to the specific recommendations of EPA relative to chlorobenzilate, the Scientific Advisory Panel proposed the following modifications:

1. We do not feel the Working Group has provided sufficient justification for the exclusion of States other than Florida, Texas, and California from the continued use of chlorobenzilate on citrus crops. Therefore, we feel all States should be allowed the continued use of chlorobenzilate on citrus crops.

2. The Scientific Advisory Panel believes the registration for use of chlorobenzilate on non-citrus crops and ornamentals should be continued on the same basis as for citrus crops. In this regard, the proposed studies concerning residues in food crops, applicator exposure, aerial application exposure, etc., required in Option F for citrus crops should also be required for non-citrus crops. The Scientific Advisory Panel believes the continued use of chlorobenzilate on non-citrus crops is justified on the basis of the fact that alternative pesticides may pose a greater potential health threat than chlorobenzilate.

3. Due to the lack of information on the potential adverse effects of chlorobenzilate on human reproduction we recommend the following studies be carried out:

a. The examination of sperm counts in a selected population of chlorobenzilate applicators.

b. A three-generation reproductive study in rats at sufficient dose levels to allow the determination of a no-adverse-effect level of chlorobenzilate on reproduction in that species. This study should be carried out using the protocol currently described in the proposed EPA guidelines for risk assessment of FIFRA chemicals.

Dated: August 17, 1978.

H. WADE FOWLER, Jr.,
*Executive Secretary,*
*FIFRA Scientific Advisory Panel.*

[FR Doc. 79-4646 Filed 2-12-79; 8:45]